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EXAMINER	
KIM, YOUNG J	
ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/590,768	JENSEN ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The present Office Action is responsive to the Amendment received on May 20, 2009.

Preliminary Remark

Claims 14-16 are new.

Claims 1-16 are pending and are under prosecution herein.

Priority

The objection to the specification for the reasons noted in the Office Action mailed on November 20, 2008 is withdrawn in view of the Amendment received on May 20, 2009.

Claim Objections

The objection of claims 1, 10, and 13 for the informalities noted in the Office Action mailed on November 20, 2008 is withdrawn in view of the Amendment received on May 20, 2009.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 10 and 11 under 35 U.S.C. 102(b) as being anticipated by Mainelis et al. (Aerosol Science and Technology, 1997, vol. 30, pages 127-144; IDS ref # 45), made in the Office Action mailed on November 20, 2008 is maintained for the reasons already of record.

Applicant's arguments presented in the Amendment received on May 20, 2009 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments" section.

The Rejection:

Preliminarily, the term, "chip" does not bear any patentably weight as a product is described solely by its physical elements, absent an explicit definition in the specification which physically describes what is considered a, "chip."

It is determined that the specification does not contain an explicit definition, and thus, any device comprising all of the claimed elements would necessarily anticipate the invention as currently claimed.

Mainelis et al. disclose a system which comprises a sample chamber comprising:

a) a first opening in connection with the surrounding air, and a second opening (see inlet and outlet, Figure 2);

b) a first and a second electrode positioned at opposing sides of the sample chamber (see electrodes on top and bottom of Figure 1); and

c) the sample chamber further comprising a liquid sample comprising biological spore (see "collection trough" in Figure 2, comprising collection medium; see page 129, 1st column, 1st paragraph; page 133, 1st column, 3rd paragraph).

The first and the second electrodes are positioned between the first and the second opening (see Figure 1).

The bacterial spore is located between the first and the second electrode (see the placement of the collection medium, Figures 1 and 2).

With regard to claim 11, the voltage which can be applied by the system is 800 V (page 129, 2nd column, 2nd paragraph).

Therefore, Mainelis et al. anticipate the invention as claimed.

Response to Arguments:

Applicants traverse the rejection.

Applicants state that the Office's characterization of the term, "chip" is erroneous in that the specification does contain definition(s) of what a "chip is" referencing sections 0015-0016, 0023, 0027, 0058, and Figure 5-8, and 11 (see page 10, 3rd paragraph, Response).

These sections have been carefully studied, but it is respectfully submitted that the description of "chip" in these sections are exemplary, and does not particularly distinguish any size of the device. While section [0015] does state that "electrostatic particle collection, e.g. performed in a microstructure, i.e., a chip", this is an example, not an explicit definition. This interpretation is consistent with the claim as claim 1 recite that the "chip" has a structure that is spaced apart as much as 20 mm. Clearly, a device which accommodates up to 20 mm in structural requirement cannot be deemed "microstructure" as implied by section [0015].

Next, Applicants contend that the chip of claim 10 as amended requires:

- a biological particle attached to the first or the second electrode, and
- a sample chamber having a volume of at most 500 uL.

Initially, it is respectfully submitted that claim neither 10 nor 11 requires that the sample chamber have any specific volume capacity.

Secondly, Applicants contend that the chip of Mainelis does not disclose that a biological particle is attached to the first or the second electrode. Apparently, Applicants are not contending that the collection chamber is located between the first and the second electrode.

Since the collection chamber is located between the first and the second electrode, it is inconceivable how at least one spore would not be attached to the either of the electrodes of the chip of Mainelis, when the air is flowed in through an opening, through a region which contains a chamber flanked by two electrodes.

Therefore, the rejection is maintained for the reasons already of record.

The rejection of claims 10-13 under 35 U.S.C. 102(b) as being anticipated by Mainelis et al. (Aerosol Science and Technology, 2002, vol. 36, pages 1073-1085; IDS ref# 47), made in the Office Action mailed on November 20, 2008 is maintained for the reasons already of record.

In addition, claim 14 is rejected herein necessitated by Amendment.

Applicants' arguments presented in the Amendment received on May 20, 2009 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments" section.

The Rejection:

Preliminarily, the term, "chip" does not bear any patentable weight as a product is described solely by its physical elements, absent an explicit definition in the specification which physically describes what is considered a, "chip."

It is determined that the specification does not contain an explicit definition, and thus, any device comprising all of the claimed elements would necessarily anticipate the invention as currently claimed.

Mainelis et al. disclose a system which comprises a sample chamber comprising:

a) first opening in connection with the surrounding air, and a second opening (see inlet, "C_{up}"; and outlet, "C_{down}");

b) a first and a second electrode positioned at opposing sides of the sample chamber (see metal plates on opposing sides of the chamber; and

c) the same chamber further comprising a liquid sample comprising biological spore (see plates with collection medium, Figure 1; page 1076, 1st column, 3rd paragraph; page 1074, 1st column, bottom paragraph).

The first and the second electrodes are positioned between the first and the second opening (see position of the openings with respect to the metal electrodes (plates); Figure 1).

The bacterial spore is located between the first and the second electrode (e.g., spores are collected in the collection medium which is located between the first and the second electrode; see Figure 1).

With regard to claim 11, the voltage of the device is disclosed as being 0 to +50 V or 0 to $\pm$ 5,000V (page 1076, 1st column, 1st paragraph).

With regard to claims 12 and 13, the artisans disclose their device, and a computer functionally associated with the device (as evidenced by Figure 1, which shows voltage fluctuations).[1]

Mainelis et al. discloses that the distance between the two electrodes is 20 mm (page 1074, 2nd column, 2nd paragraph) ,with distance between the agar surface and the top electrode in the precipitation section being 5 mm (page 1074, 2nd column, 2nd paragraph).

Therefore, Mainelis et al. anticipate the invention as claimed.

Response to Arguments:

[1] The limitation, "functionally associated with a device according to claim 12," does not necessarily require that the system of claim 13 actually contain in its housing the device, but rather that it can simply be connected by wires or by some other connection means to a device comprising the programmable unit. Mainelis et al. evidences that the device of the artisans were functionally associated with the computer which calculated and outputted varying voltages on to their electrodes during experimentation.

Applicants traverse the rejection.

Applicants state that the Office's characterization of the term, "chip" is erroneous in that the specification does contain definition(s) of what a "chip is" referencing sections 0015-0016, 0023, 0027, 0058, and Figure 5-8, and 11 (see page 10, 3rd paragraph, Response).

These sections have been carefully studied, but it is respectfully submitted that the description of "chip" in these sections are exemplary, and does not particularly distinguish any size of the device. While section [0015] does state that "electrostatic particle collection, e.g. performed in a microstructure, i.e., a chip", this is an example, not an explicit definition. This interpretation is consistent with the claim as claim 1 recite that the "chip" has a structure that is spaced apart as much as 20 mm. Clearly, a device which accommodates up to 20 mm in structural requirement cannot be deemed "microstructure" as implied by section [0015]. In addition, the device disclosed by Mainelis also accommodates a 20 mm separation between the two electrodes, which appears to be very close to the separation distance allowed by the instantly rejected claims.

Next, Applicants contend that the chip of claim 10 as amended requires:

- a biological particle attached to the first or the second electrode, and
- a sample chamber having a volume of at most 500 uL.

Initially, it is respectfully submitted that claim neither 10 nor 11 requires that the sample chamber have any specific volume capacity.

Secondly, Applicants contend that the chip of Mainelis does not disclose that a biological particle is attached to the first or the second electrode. Apparently, Applicants are not contending that the collection chamber is located between the first and the second electrode.

Since the collection chamber is located between the first and the second electrode, it is inconceivable how at least one spore would not be attached to the either of the electrodes of the

chip of Mainelis, when the air is flowed in through an opening, through a region which contains a chamber flanked by two electrodes.

Next, Applicants state that the Office Action completely disregards two of the elements of claim 10, as well as in Claim 13 (page 10, bottom paragraph, Response).

Initially, Applicants' concern regarding the two elements in claim 10 has already been addressed above.

Applicants state that claim 13 has the limitation discussed in page 11, 1st paragraph of their Response. This is inaccurate because claim 13 is dependent from claim 10, and the limitations which Applicants are arguing in found on claim 12.

Claim 13 is simply drawn to a system for collecting biological particles, comprising a chip of claim 10. To this end, Applicants' attention is drawn to Figure 3.

As to the limitation of claim 12, it is respectfully submitted that Mainelis does disclose all of the limitation of claim 12.

Claim 12 is drawn to a device comprising:

a) a chip site where the chip is to be located; and

b) a programmable unit comprising a software that effects that the device perform at least one of applying electrical field.

Applicants' attention is again drawn to Figure 3. The device (the entire set up of Figure 3) is functionally associated with the electrostatic precipitator is situated at a particular location (i.e., site).

With regard to a programmable unit, it is respectfully submitted that the electrostatic precipitator would necessarily have a computerized component which controls and maintains the electrostatic field being applied in the electrostatic precipitator.

Lastly, with regard to Applicants' statement drawn to the instant device not requiring any charging, this statement is not found persuasive because the product is only examined to the extent of their structural limitations, not how it is used. Claims require that the product have a sample chamber and a first and second electrodes which are positioned at opposing sides of the sample chamber, wherein said first and second electrodes are separated by at most 20 mm. These limitations are clearly met by the device disclosed by Mainelis.

Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103 - Maintained

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Birmingham et al. (U.S. Patent No. 5,989,824, issued November 23, 1999) in view of Mainelis et al. (Aerosol Science and Technology February 2002, vol. 36, pages 1073-1085; IDS[2] ref# 47), made in the Office Action mailed on November 20, 2008 is maintained for the reasons already of record.

Applicants' arguments presented in the Amendment received on May 20, 2009 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments" section.

The Rejection:

Birmingham et al. disclose a method of detecting biological particles from gaseous sample (Air, see Figure 1, elements 14 and 16), said method comprising:

[2] IDS received on January 26, 2007

a) providing said gaseous sample into a sample collector and concentrator (thus a sample chamber; Figure 2B, element 50 "fluid flow" – column 6, lines 27-28);

b) contacting the collected biological particle (spores, see column 2, lines 46-47) with a liquid agent (column 2, lines 60-62, in the phrase, "[i]n an alternative preferred embodiment, the ionizing discharge is employed to ionize a fluid, producing an ionized fluid that ruptures the surface membrane of the cell.");

c) exposing said liquid agent to an electric field in the sample chamber (column 2, line 66 to column 3, line 2, in the phrase, "the cell is conveyed past an ionizing discharge from an electrode that lyses the cell.") having a sufficient amplitude so as to enable extraction of biological material from the biological particle (column 4, lines 54-60, in the phrase, "[t]he spore lysing apparatus, which is configured in accord with the present invention, facilitates cleavage and rupturing of the surface membrane around each of the bacterial cells and/or spores comprising the specimen…it is important to expose the DNA and RNA comprising the nuclear material contained within the surface membrane of these bacterial spores and cells"; column 6, lines 61-65);

d) performing analysis of the extracted biological material (column 5, lines 3-4), wherein the artisans explicitly state that device comprise those which conducts (PCR, column 5, line 29-32), which would result in the measurement of the amplified nucleic acid sequence (column 5, lines 31-33).

Birmingham et al. do not explicitly disclose that a first and second electrode is provided and that the chamber is positioned so that at least part of the sample chamber is between the first and the second electrode, and that a potential is applied to the first and second electrode so as to assist electrostatic collection of the biological sample into the chamber.

Birmingham et al. do not explicitly disclose that the distance between the first and the second electrode is at most 20 mm or at most 10 mm.

Birmingham et al. do not explicitly disclose that the electric field applied between the first and the second electrode yields in a capture efficiency of at least 50% for biological particles having an effective length in the interval from 1-10 micrometer.

While Birmingham et al. disclose a device which collects, lyses, and conducts DNA/RNA analysis on a single chip, the artisans do not explicitly state that a device comprising a first and a second electrode, a heating electrode, and a temperature sensing element, nor an apparatus configured for such a purpose.

Mainelis et al. disclose a device comprising 2 electrodes, spaced at a distance of 20 mm (page 1074, 2nd column, 2nd paragraph; page 1075, Figure 1A, height, "H"), wherein the artisans employ said device to generate an electrical field, for the purpose of collecting bacterial spores from air samples (thus gaseous; see page 1077, 1st column, 4th paragraph).

Mainelis et al. analyzes bacterial spores of *Bacillus* (page 1076, 1st column, bottom paragraph).

Mainelis et al. discloses that the distance between the two electrodes is 20 mm (page 1074, 2nd column, 2nd paragraph) ,with distance between the agar surface and the top electrode in the precipitation section being 5 mm (page 1074, 2nd column, 2nd paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Birmingham et al. with the teachings of Mainelis et al., thereby arriving at the claimed invention for the following reasons.

The motivation to arrive at a device which conducts the steps of collecting biological spores from gaseous sample, followed by their lysis with an electrical field, and followed by their analysis,

for the advantage of producing portable devices for military usages, has been known in the art, as clearly expressed by Birmingham et al.:

> "One of the more important applications of technology requiring the lysing of bacterial cells and/or spores is in facilitating identification of biological agents that are used during bacteriological warfare or in attacks by terrorists. In order to permit known harmful bacteria to be identified, it is important that DNA and RNA comprising the bacterial cells or spores found in the suspect environment be made available for analysis. By providing a reliable and portable apparatus for lysing bacteria cells or spores collected from the environment, it will be possible to identify bacteriological warfare agents in the field so that appropriate counteractive and protective measures can be implemented. A portable field monitoring device that includes the capability to collect, concentrate, lyse, and identify bacteriological warfare agents will greatly enhance the ability of civilian populations and troops to survive such attacks." (column 2, lines 24-39, Birmingham et al.)

As discussed already above, Birmingham et al. disclose a method and a use of a device that collects the air sample by flow into the device, followed by the lysis of the bacterial spores therein via electric field, followed by the analysis of the extracted DNA/RNA therefrom.

While Birmingham et al. do not employ a first and a second electrode which is spaced apart for the initial capture of the bacterial spores, one of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of Mainelis et al., wherein the artisans state that with the use of electrostatic capture method, they were able to achieve about 90% collection efficiency (page 1078, 1st column) when collecting bacterial spores from a gaseous sample.

Figure 3 of Mainelis et al. clearly show the efficiency rate collection of bacterial spores from air with the electrostatic enhancement versus no electrostatic enhancement (see collection efficiency with voltage near zero).

Since the invention disclosed by Birmingham et al. was focused on the detection of biological warfare agents in the field, one of ordinary skill in the art would have recognized that

collection efficiency of the bacterial spores in the air would have been a critical element, allowing for higher sensitivity in detection of harmful agents in the air.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of Birmingham et al. with the teachings of Mainelis et al., so as to arrive at a device and a method of using said device for the efficient capture of bacterial spores from air, followed by their lysis, and subsequent analysis of the DNA/RNA typing, with a reasonable expectation of success.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Response to Arguments:

Applicants traverse the rejection.

Applicants initially contend that Birmingham uses "ionized discharges" and "gases" not electrodes or electric fields and liquids, and thus does not teach or suggest the purported corresponding elements of the claims.

Applicants make similar arguments through pages 12-14, concentrating on the Birmingham reference.

To this end, Applicants are advised that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants reference page 7 of the Office Action wherein it was alleged that Birmingham disclosed contacting a collected biological particle with a liquid agent, arguing that while Birmingham uses the term, "fluid" the artisans are using the term to describe gases and air, not "liquid." (page 15, 1st paragraph, and page 16 Response).

Applicants' assessment of the Birmingham reference is correct.

However, it is respectfully submitted that the rejection of record still stands based on the entire disclosure of Birmingham.

The motivation to combine the teachings of Birmingham with the teachings of Mainelis is in that Birmingham **clearly** provides a reason, motivation and advantage of designing a chip/device which is portable, said chip/device which is capable of collecting samples of air, retrieve bacterial spores therefrom, lyse said spores, then analyze and determine the contents therein all in a single device:

> "***One of the more important applications of technology requiring the lysing of bacterial cells and/or spores is in facilitating identification of biological agents that are used during bacteriological warfare or in attacks by terrorists***. In order to permit known harmful bacteria to be identified, ***it is important that DNA and RNA comprising the bacterial cells or spores found in the suspect environment be made available for analysis***. ***By providing a reliable and portable apparatus for lysing bacteria cells or spores collected from the environment, it will be possible to identify bacteriological warfare agents in the field so that appropriate counteractive and protective measures can be implemented***. ***A portable field monitoring device that includes the capability to collect, concentrate, lyse, and identify bacteriological warfare agents will greatly enhance the ability of civilian populations and troops to survive such attacks***." (column 2, lines 24-39, Birmingham et al.)

Note the statement made by Birmingham wherein the artisans state that a, "portable field monitoring device that includes the capability to collect, concentrate, lyse, and identify bacteriological warfare agent" will **"greatly enhance"** the ability of civilian populations and troops to survive such attacks.

So, there is ***no question*** that one of ordinary skill in the art would have been motivated to arrive or design a single device which is capable of collecting, concentrating, lysing, and identifying from air samples.

Applicants' instantly claimed method does exactly that.

Applicants' instantly claimed method, provides a sample chamber that:

a) collects and concentrates biological particle from air;

b) allows liquid to be contacted with the collected particle; and

c) identification of the particle.

Since Applicants' claimed method achieves the same steps as performed by Birmingham et al., the question of obviousness falls on whether the means of achieving the three steps (i.e., collect/concentrate, lyse, and detect) were known and available in the prior art and whether said one of ordinary skill in the art would have had a reasonable expectation of success at combining the prior art elements so as to arrive at the claimed invention.

Such analysis is consistent with that which was discussed by the Supreme Court in *KSR International Co. v. Teleflex Inc* (*KSR*):

> "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results" *Id.* at __ 82 USPQ2d at 1395.

Since the motivation design ***a single device*** which collects/concentrates, lyses, analyzes a biological particle from air was **clearly present**, the question lies on whether said one of ordinary skill in the art would have been motivated to employ other prior art known means to achieve the same steps performed by Birmingham et al.

And as discussed above, the art of employing electric field generated between two electrodes had been known in the art, as evidenced by Mainelis. Therefore, said one of ordinary skill in the art would have had no reason to doubt that a sample chamber located between two electrodes would have resulted in the same means of "collecting and concentrating the bacterial spores" of Birmingham et al.

Such combination would have produced a device which comprises a sample chamber flanked by two electrodes, wherein air sample is flowed through in inlet, and the bacterial spores are collected/concentrated between the two electrodes in the sample chamber, achieving steps (a) through (c) of claim 1.

Next step of claim 1 - step (d) requires that this collected biological sample is "contacted" with a "first liquid."

As Applicants correctly argue, the term, "fluid" employed by Birmingham is not "liquid," but rather, gases.

However, Birmingham discloses the following:

> "As the present invention is likely to be actually practiced, the sample of bacterial cells and/or spores that is collected from the environment will preferably be deposited on metal coupon … lysed, and the bacterial cells and/or spores identified without moving the coupon." (column 4, lines 30-34)

Therefore, from this section of the disclosure, it is clear that the device disclosed by Birmingham motivates the one of ordinary skill in the art to collect/concentrate, lyse and identify in the ***same*** space.

In addition, in contemplating the various types of "identification" process which is to be done by their (Birmingham's) device, the artisans explicitly contemplate PCR (column 5, line 29-32), and measuring the amplified nucleic acid sequence (column 5, lines 31-33).

Therefore, one of ordinary skill in the art would have recognized that the same space of Birmingham wherein the sample is collected/concentrated, lysed, and identified would have allowed liquid to be employed (since PCR requires buffers and reagent mix).

In *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342 (CCPA 1968), the court expressed that, "in considering the disclosure of a reference, it is proper to take into account not only specific teachings

of the reference but also the inference which one skilled in the art would reasonably be expected to draw therefrom."

To reiterate, Birmingham already demonstrated a motivation and a device which is capable of collecting/concentrating, lysing, and identifying biological particles from air, with the only exception that the collection means employed by Birmingham was by ionized discharge. However, the art of collecting and concentrating biological particles from air was known in the prior art, as evidenced by Mainelis.

Therefore, one of ordinary skill in the art would have been motivated to combine the teachings of Birmingham with the teachings of Mainelis as such combination would have yielded no more than a predictable result of successful collection/concentration of biological particles from air into a chamber.

Elsewhere in *KSR* the Supreme Court expressed the following:

> "A person of ordinary skill in the art is also a person of *ordinary creativity*, not an automation" (82 USPQ2d at 1397) and that "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle" and take into account, "the inference and creative steps that a person of ordinary skill in the art would employ" (82 USPQ2d at 1396).

Next, Applicants contend that there is no motivation to or from either Birmingham or Mainelis 2002 to substitute two electrodes and an associated electric field therebetween for an ionizing discharge generator. (page 17, 3rd paragraph, Response).

It is respectfully submitted that the motivation for employing the means disclosed by Mainelis is for achieving the same means, that is, collecting/concentrating biological particles from air into a particular environment. As previously discussed, one of ordinary skill in the art would have expected that any prior art means of collecting/concentrating biological particles from air

would have equally worked well. Since Birmingham already provides a single device which is capable of collecting/concentrating/lysing/identifying biological particles from air, substituting one of the means for other prior art known means would have been obvious to one of ordinary skill in the art, yielding "no more than predictable results."

As to Applicants' statement regarding there being no motivation to achieve a liquid reagent mixture, Applicants' attention is directed to the above discussion wherein Birmingham clearly implies that liquid reagents be handled by their device.

As to Applicants' arguments which imply that Mainelis and Birmingham reference each other's teachings for motivation to be present, such understanding is simply erroneous.

Therefore, for the above reasons, it is respectfully submitted that the invention as claimed is deemed *prima facie* obvious over the cited references.

The rejection of claims 9-13 under 35 U.S.C. 103(a) as being unpatentable over Birmingham et al. (U.S. Patent No. 5,989,824, issued November 23, 1999) in view of Mainelis et al. (Aerosol Science and Technology February 2002, vol. 36, pages 1073-1085; IDS[3] ref# 47), as applied to claims 1, 2, and 17 above, and further in view of Johns et al. (Letters in Applied Microbiology, 1994, vol. 18, pages 236-238; IDS[4] ref# 38), made in the Office Action mailed on November 20, 2008 is maintained for the reasons already of record.

In addition, claims 14-16 included herein as being necessitated by Amendment.

Applicants' arguments presented in the Amendment received on May 20, 2009 solely rely on the previously addressed arguments which have been fully rebutted above.

Therefore, the rejection is maintained for the reasons already of record.

The Rejection:

The teachings of Birmingham et al. and Mainelis et al. have already been discussed above.

Birmingham et al. do not explicitly disclose a chip configured for such a purpose, or that a device which is configured for housing such a chip be produced.

Johns et al. disclose a method of detecting *Bacillus anthracic* in spores by use of PCR (Abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Birmingham et al. and Mainelis et al., with the teachings of Johns et al., thereby arriving at the claimed invention for the following reasons.

Birmingham et al., while not explicit in stating that a PCR be conducted for the DNA/RNA analysis followed by the spore lysis and extraction of DNA/RNA therefrom, the artisans clearly imply any type of DNA/RNA analyses available in the art could be employed:

> "Once the surface membranes of the bacterial cells and/or spores have been ruptured by lysing apparatus...,the exposed nuclear material comprising specimen…is carried by conveyer...to a spore or cell RNA/DNA identifier...This identifier processes the nuclear material to identify the specific type of bacterial cells and/or spores comprising the specimen. The device preferably used for identifying the type of bacteria in the specimen is a time of flight mass spectrometer. However, a number of other types of bacterial spore and cell identifiers might alternatively be used..." (column 5, lines 1-10, Birmingham et al.)

Johns et al. clearly demonstrate to one of ordinary skill in the art the need to detect anthrax and a particular method of its detection - polymerase chain reaction (Abstract) - wherein the artisans extract DNA from spores of anthrax, and conducts PCR (page 236, 2nd column).

The artisans state that the disruption of the spores prior to the PCR amplification provided faster and sensitive result (page 237, 2nd column, Johns et al.):

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[3] IDS received on January 26, 2007

> "Germination of spores in PBS/150 mmol/l L-alanine/6 mmol/l OCDS prior to PCR increased sensitivity to allow for the detection of 10 spores per test. But although this procedure gave very sensitive PCR result, it was slow. As mechanical disruption might be more rapid, we decided to evaluate the use of … to mechanically disrupt spores...Equivalent sensitivity in PCRs from germinated and mechanically disrupted spores..." (page 237, 2nd column, Johns et al.).

Therefore, one of ordinary skill in the art at the time the invention was made would have clearly recognized that the use of PCR for identifying bacterial spores, wherein said spores have been disrupted, would have yielded their sensitive detection.

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success at producing the combine invention given the fact that Birmingham et al. identifies the extracted DNA/RNA from the bacterial spores by first lysing said spores. Since Johns et al. clearly demonstrate that PCR can be conducted from lysed spores of anthrax, one of ordinary skill in the art would have been motivated to combine the teachings of the artisans, thereby arriving at the invention as claimed.

With regard to the limitations drawn to the chip, which is configured for conducting these steps on an integrated device and an apparatus which houses such a chip, it is respectfully submitted that the art is replete with miniature-integrated devices, which conducts a plurality of biological assays (i.e., microfluidics, microfabricated devices) and apparatus which analyzes such devices.

Therefore, the Office is taking official notice for this teaching. Should Applicants challenge this fact, such evidence would be provided in a subsequent Office Action, but nevertheless be made final.

MPEP 2144.03(D) states the following in such a situation:

> "If the examiner adds a reference in the next Office action after applicant's rebuttal, and the newly added reference is added only as directly corresponding evidence to support the prior

> common knowledge finding, and it does not result in a new issue or constitute a new ground of rejection, the Office action may be made final."

Given the motivation provided for by Birmingham who provides motivation for electrostatic capture/rupture of bacterial spore for analysis of their contents, followed by the explicit teaching provided for by Mainelis et al. who teach an electrostatic capture of bacterial spore between two electrodes, one of ordinary skill in the art would have been clearly motivated to arrive a device of the instantly claimed invention.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to arrive at the device and apparatus for conducting the method of the combined teachings of the artisans, as the motivation to conduct such a method would have been present to said one of ordinary skill in the art, and producing a device/apparatus for such a purpose would have been well within the purview of an ordinarily skilled artisan.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Double Patenting

The provision rejection of claims 10-13 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/590,630, made in the Office Action mailed on November 20, 2008 is withdrawn. Specifically, the claims drawn to the chip and device have been canceled in the conflicting application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application

claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1-9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/590,630, made in the Office Action mailed on November 20, 2008 is maintained for the reasons already of record.

Applicants have not submitted a proper terminal disclaimer for the present rejection. Therefore, the rejection will be maintained herein.

The provisional rejection of claims 1-13 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/590,632, made in the Office Action mailed on November 20, 2008 is maintained for the reasons already of record.

Applicants have not submitted a proper terminal disclaimer for the present rejection. Therefore, the rejection will be maintained herein.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 9:00 a.m. to 5:30 p.m (M-F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by

applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Young J. Kim/
Primary Examiner
Art Unit 1637
8/10/2009

/YJK/